

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

Mr. Behravesh and the undersigned appreciate the interview that Mr. Behravesh had with Examiner Menon on April 28, 2004. The substance of the interview is incorporated in the remarks set forth below.

At page 2 of the Office Action, the Examiner rejects claims 1-9, 11, 13-16, 19-25, 29-38, and 50-61 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. (U.S. Patent No. 4,650,587) in view of the applicant's own disclosure of the REDY cartridge. According to the Examiner, Polak et al. describes a sorbent comprising at least one sodium zirconium carbonate (SZC) as recited in claims 1 and 11 of the present application. The Examiner indicates that Polak et al. describes a capsule, and not layers, comprising SZC. However, the Examiner asserts that the applicant's disclosure of the REDY cartridge describes sorbents configured as layers in a cartridge. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of invention, to use the teachings of the REDY cartridge in Polak et al.

At page 9 of the Office Action, the Examiner responds to the Amendment dated October 15, 2003. According to the Examiner, in the Amendment dated October 15, 2003, the applicant argued that Polak et al. does not teach or suggest using a layered structure and never once taught ZrP with SZC. In response, the Examiner states that Polak et al. describes ZrP as prior art. Furthermore, the Examiner states that Polak et al. does not teach away from ZrP. According to the Examiner, magnesium phosphate product (MGP) is taught as an alternative or improvement over

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

ZrP. Furthermore, the Examiner states that having the material in a pouch does not make it any less layered.

The Examiner also states that the fact that the applicant has recognized another advantage, which would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious. Furthermore, the Examiner emphasizes that Polak et al. describes a layered structure by the myriads of references cited therein, which, according to the Examiner, show a layered structure. For the following reasons, this rejection is respectfully traversed.

The claimed invention relates in part to a sorbent cartridge comprising at least two layers, wherein one of the layers comprises at least SZC in the sorbent cartridge. Furthermore, the claimed invention relates to a sorbent cartridge comprising an alkali metal-Group IV B metal carbonate, wherein the alkali metal-Group IV B metal carbonate is present as a layer in the sorbent cartridge.

Polak et al. relates to a particulate magnesium phosphate product (MGP) and to a method for removing ammonia from aqueous solutions. According to Polak et al., the MGP can be utilized as a replacement for ZrP materials, which are used to remove ammonia produced by enzymatic hydrolysis of urea in recirculating dialysis systems utilizing disposable cartridges. Therefore, contrary to the Examiner's statements, Polak et al. does not teach or suggest using a layered structure, and never once teaches ZrP with SZC. Columns 5 and 6 of Polak et al., which the Examiner relies upon, only shows MGP with SZC. Polak et al. does not teach or suggest that the SZC is present as a layer in a sorbent cartridge. SZC is never used alone in Polak et al. Polak et al. requires that SZC be used with MGP. See Figure 2 and column 6, lines 9-11. Polak et al. only

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

describes a mixture of MGP and SZC components in a pouch. Moreover, Polak et al. uses magnesium phosphate with a SZC and discourages the use of ZrP. There is no teaching in Polak et al. to use ZrP with SZC, especially in any layered configuration.

In one example of the present application, the SZC layer is, in part, a phosphate adsorbent, which can remove phosphate from a renal disease patient for the treatment of hyperphosphatemia. Preferably, SZC produces bicarbonates that can be delivered to a patient for correcting the metabolic acidosis. Furthermore, the SZC layer preferably buffers the acidity of the dialysate caused by the lattice hydrogen ions of ZrP and hydrous zirconium oxide (HZO), which will otherwise decompose the bicarbonate dialysate and lower the bicarbonate level of the patient.

The layer structure of the claimed invention is based on the principle of adsorption column design to ensure high adsorption efficiency. A blended mixture of components, especially a blended mixture of ZrP and SZC, will not only cause a high level of phosphate leakage, but also can cause a rapid uncontrolled reaction that produces CO₂ gas during application.

With respect to the Examiner's reply to the Amendment dated October 15, 2003, that Polak et al. describes ZrP as prior art, although the references cited in Polak et al., such as U.S. Patent No. 3,669,880, describe a cartridge having a ZrP layer, the references simply do not teach or suggest the use of an SZC layer in combination with a ZrP layer. Polak et al. even discourages the use of ZrP due to its disadvantages as mentioned at col. 3, lines 11-36; and col. 4, lines 38-48, and the references cited within Polak et al. One skilled in the art would conclude that SZC can only be used

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

in combination with MGP and not with ZrP. In addition, none of the references in Polak et al. shows the use of SZC as a layer.

Further, the REDY cartridge includes layers, whereas the cartridge of Polak et al. does not. How the REDY cartridge can be combinable with Polak et al. is not seen. The features of the claimed invention in these claims are unique in the sense that the features in the claimed invention are based on the combination of the ZrP with SZC, wherein the SZC is present as a layer. The SZC layer and the ZrP of the claimed invention preferably function to adjust the Na⁺ and bicarbonate of the regenerated dialysate to the right level; therefore, allowing the use of the cartridge for other treatments and a broader range of dialysis conditions. As is mentioned above, Polak et al. describes a mixture of MGP and SZC components in a pouch. However, in the claimed invention, the SZC is used in the form of a layer and ZrP is present to assist in regenerating dialysate to preferred levels. Further, one cannot simply replace the layers in the REDY cartridge with the material of Polak et al. and expect success. At best, this is an improper obvious to try standard. This is especially true when ZrP is not used in Polak et al. and layers are not present. Neither reference provides any teaching, suggestion, or motivation to make such layer substitutions. The Examiner cannot simply pick and choose layers and design a cartridge to reject the claimed invention when the prior art does not provide this motivation. The Examiner is improperly using hindsight to arrive at this conclusion. The REDY cartridge disclosure and Polak et al. do not suggest such a substitution.

Additionally, one skilled in the art, after reviewing the teachings of Polak et al. and the REDY cartridge, would not be motivated to replace HZO of the REDY cartridge with SZC. Neither

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

Polak et al. or REDY teach or suggest such a substitution. Where is the suggestion in the cited references? In fact, based on the high level of phosphate leakage created by having a blended mixture of ZrP and SZC, one skilled in the art would prefer to use HZO instead of SZC.

With respect to many of the dependent claims, the Examiner takes the position that these specific properties would be obvious. However, the Examiner does not provide any specific reasons for concluding that these properties would be obvious and has not even provided any technical reason for why these properties would be inherent. Simply because a similar general material may be mentioned in a reference does not mean that the compound has the same properties. There has to be a technical basis for concluding obviousness or for asserting inherency. It is not enough for the Examiner to simply say that the same material is automatically used when clearly the present invention, especially the claims of the present invention, set forth precise chemical properties or amounts which clearly are not taught or suggested in the cited art. The Examiner at times asserts that certain characteristics are "a material property," and therefore concludes obviousness. However, a material property that is not taught or suggested in the cited art is clearly reason enough for patentability. There are many patents that would attest to this standard. Without any further technical basis, the Examiner's rejections of these claims should be withdrawn.

In addition, with respect to the Examiner's comments, for instance, concerning claim 16 that the order of layers is not taught in the REDY cartridge since the position of granulated activated carbon layer is not the same, the Examiner's comments are not understood. Even if the applicant states in the present specification that the activated carbon layer can be in any order, claim

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

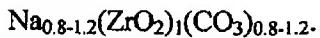
16 does not recite this. Claim 16 recites a specific order of layers which clearly is not shown in the cited references as admitted by the Examiner. The Examiner cannot use the applicant's own disclosure for purposes of rejecting the claims. Clearly, the Examiner's rejection is in error.

In addition, with respect to claim 20, wherein the Examiner states that the material of Polak et al. would satisfy the ANSI/AAMI standard, again, the Examiner has not even shown that the material is the same and therefore, one cannot conclude that it would satisfy such a requirement. This is especially true when the material used in Polak et al. is not even used as a layered structure.

With respect to the Examiner's rejection of claims 29-31 wherein the Examiner asserts that the "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art," first of all, the applicant respectfully points out that the claims being rejected are product claims and not process claims. Thus, the Examiner's argument does not apply.

In addition, the sorbent cartridge claims are not "a known process" or a known product. As pointed out above, clearly Polak et al. does not teach or suggest these amounts which are present in a layered structure. Since the purpose and design of Polak et al. is not even close to the claimed invention, one cannot assert that this is a mere optimization issue. Clearly, these amounts have relevance as shown in the present application and the relevance of these amounts are clearly not taught or suggested in Polak et al. or by the Examiner's reliance on REDY.

In addition, the applicant respectfully points out that the sodium zirconium carbonate product set forth in Polak et al., as described at the top of column 6, has the formula



On the other hand, this formula clearly would not be covered, for instance, by the sodium

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

zirconium carbonate set forth in claim 19.

With respect to the Examiner's argument that having the material in a pouch does not make it any less layered, at page 3 of the Office Action the Examiner specifically states that Polak et al. does not disclose layers comprising Szc. Further, claim 1 specifically recites two layers, one of which is Szc. Where are the two layers in Polak et al? The Examiner, at page 5 of the Office Action, further emphasizes that Polak et al. does not describe layers comprising Szc by stating that Polak et al. does not teach how the absorbents are structured in the cartridge. Accordingly, this rejection should be withdrawn.

At page 7 of the Office Action, the Examiner rejects claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge and further in view of Potts (U.S. Patent No. 5,234,603). The Examiner, for the most part, repeats the reasons for rejecting claims 26-28 as set forth in the Office Action dated July 16, 2003. In addition, the Examiner states that Potts, at col. 4, line 35, describes that the zirconium carbonate would hydrolyze to form a polymeric oxide chain.

At page 10 of the Office Action, the Examiner responds to the Amendment dated October 15, 2003. According to the Examiner, in the Amendment dated October 15, 2003, the applicant argued that Potts and Polak et al. are not within the same field of endeavor. In response, the Examiner states that the Zr compounds are considered ion exchange materials, as well as having use in dialysis, as taught by Polak et al. and Potts. Therefore, Polak et al. and Potts are well within the field of the applicant's endeavor. For the following reasons, this rejection is respectfully traversed.

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here.

Further, Polak et al. relates to the preparation of magnesium phosphates and their use in the medical field, their use in recirculating dialysis systems and other systems having the purpose of removing urea/ammonia from bodily fluids, and in wastewater treatment to remove ammonium ions. In contrast, according to Potts, at column 3, lines 55-61, the contaminants to be removed include actinide and lanthanide metals, transition metals, heavy metals, suspended solids (either organic, inorganic, and/or biological), alkaline earth metals, and similar insoluble materials (and materials which can be made insoluble) in the wastewater. Potts does not teach or suggest removal of urea or ammonia.

Furthermore, the zirconium carbonate in Potts is not used as an ion-exchange material to remove contaminants from wastewater. In fact, a reading of Potts indicates that its zirconium carbonate is used as a precipitating agent by itself or in combination with a coagulating agent, a reducing agent, or a weighting agent. Thus, the zirconium carbonate of Potts must be a soluble salt. Therefore, zirconium carbonate of Potts cannot form a layer in a sorbent cartridge. The two references are simply not within the same field of endeavor. Accordingly, one skilled in the art seeking to learn about the removal of urea/ammonia from bodily fluids would not look to Potts. The Examiner cannot use hindsight to mix and match the layers. Absolutely no suggestion is made in either reference for mixing and matching the layers. Accordingly, this rejection should be withdrawn.

At page 8 of the Office Action, the Examiner rejects claims 17 and 18 under 35 U.S.C.

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

§103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Marantz et al. (U.S. Patent No. 3,669,880). The Examiner, for the most part, repeats the reasons for rejecting claims 17 and 18 as set forth in the Office Action dated July 16, 2003. The Examiner further states that Marantz et al. is used to show a flow distributor and filter pads. Furthermore, at page 11 of the Office Action, the Examiner states that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. According to the Examiner, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here.

Marantz et al. relates to a recirculating dialysate system for use with an artificial kidney in which the total volume of dialysate solution is controlled. According to Marantz et al., the urea in the solution is removed in a ZrP column, and the other waste products are removed in the carbon column containing activated carbon and hydrated zirconium oxide. In contrast, Polak et al. teaches away from Marantz et al. by replacing the ZrP with magnesium phosphate. Thus, one skilled in the art, by reading Polak et al., would conclude that since the composition of Polak et al. is different from Marantz et al., the cartridge used in Marantz et al. would not work in Polak et al. Therefore, one skilled in the art would not be motivated to combine Polak et al. and Marantz et al.

Furthermore, Marantz et al. has an issue date of June 13, 1972 and Polak et al. has an issue

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

date of March 17, 1987. As indicated on the face page of Polak et al., the inventors of Polak et al. were well aware of Marantz et al. However the inventors of Polak et al. did not incorporate the fluid distributor and filter pads of Marantz et al. in Polak et al. Thus, clearly one of ordinary skill in the art would not have been motivated to combine the teachings of Polak et al. in view of the REDY cartridge with the teachings of Marantz et al. Accordingly, this rejection should be withdrawn.

At page 8 of the Office Action, the Examiner rejects claim 10 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Tawil et al. (U.S. Patent No. 4,025,608). The Examiner, for the most part, repeats the reasons for rejecting claim 10 as set forth in the Office Action dated July 16, 2003. Furthermore, the Examiner states that zirconium phosphate made by any process would still be a zirconium phosphate unless the applicant can show a significant difference in the structure or the chemical composition of the product made by the different process. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here.

Tawil et al. relates to a ZrP that is made by reacting a zirconium salt with a phosphoric acid or a phosphate in a liquid medium, wherein the zirconium salt is insoluble in water. The Examiner cannot simply substitute different particles and argue that the substituted particles automatically have the same size as the original particles. No support exists for such a conclusion. According to Tawil et al., at column 2, lines 54-59, the grain size of the ZrP is at least 30 microns. As discussed above, Polak et al. even teaches away from utilizing a ZrP. Thus, one skilled in the art, when

U.S. Patent Application No. 09/996,505
Request for Reconsideration dated May 3, 2004
Reply to final Office Action dated December 3, 2003

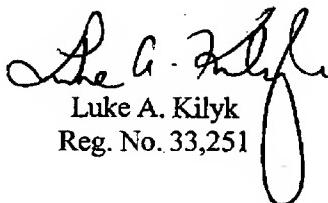
reading Polak et al., would not be motivated to look to Tawil et al. for any guidance. Furthermore, as stated earlier, one skilled in the art would not combine the teachings of Polak et al. with the REDY cartridge, and, even if combined, a mixture of various components, and not layers, would be used. Therefore, one skilled in the art would not be motivated to combine Polak et al. with the REDY cartridge and Tawil et al. to derive claim 10 of the present application. Accordingly, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3192-002
KILYK & BOWERSOX, P.L.L.C.
53 A East Lee Street
Warrenton, VA 20186
Tel.: (540) 428-1701
Fax: (540) 428-1720